



# THE TISSUE ISSUE:

## Ethical and Legal Issues in Biorepository Research

Sponsored by the Arizona Biomedical Research Commission, the Flinn Foundation and the Arizona Hospital and Healthcare Association

## An Arizona Translational Resource Network (AzTransNet) Policy Development Retreat

### WHEN?

**Wednesday, January 31, 2007**  
from 8:00 a.m. – 4:30 p.m.

### WHERE?

**The Phoenix Airport Marriott**  
1101 North 44th Street  
Phoenix, AZ 85008  
602-273-7373

Limited rooms have been reserved at a special rate

### QUESTIONS?

Contact Pam Mitchell  
Battelle  
pimitchell@aol.com  
831-901-4011  
or Kristen Rosati,  
Coppersmith Gordon Schermer &  
Brockelman PLC  
krosati@cgsblaw.com  
602-381-5464

### REGISTRATION INFORMATION?

Registration is available online at [www.azhha.org/public/education](http://www.azhha.org/public/education) and click on Program Calendar. For questions regarding registration please call 602-445-4356 or email [edservices@azhha.org](mailto:edservices@azhha.org)

AzHHA Member rate: \$75

Individual rate: \$75

Faculty/Student rate: \$50

### Registration deadline is Friday, January 26, 2007

Registrations made after this date will incur a \$25 late fee.

**Cancellation Policy:** Cancellations received at least 5 business days prior to the event will receive a full refund, less a \$25 administrative processing fee. After this date, refunds will not be given but alternates from the same organization may be substituted.

**Why?** The “Tissue Issue” looms large in Arizona, as more researchers seek to collect serum and tissue (biospecimens) to include in research repositories and as Arizona institutions create extraordinary biospecimen collections. Many hospitals, physician practices, and research sites are uncertain of the legal and ethical issues involved in providing biospecimens to third party research repositories or in storing biospecimens in their own repositories.

**What?** The Biorepository Research Policy Development Retreat is designed to thoroughly explore these legal and ethical issues, including:

- Seeking informed consent and responding to requests to withdraw consent
- Protecting the privacy of donors: HIPAA and Common Rule regulatory requirements
- Considering community interests in biorepository research
- Dealing with the business of biospecimens: drafting Material Transfer Agreements; recognizing and handling the intellectual property issues and dealing with ownership
- Determining when the use of stored pathology specimens become “research”

After the Retreat is completed, the Arizona Translational Resource Network (AzTransNet) will convene a policy development working group to develop template policies and procedures, informed consent documents and HIPAA authorization forms to harmonize the approach of Arizona institutions to biospecimen research. We hope a common approach to biospecimens will increase research collaboration among Arizona providers and research institutions.

**Who?** The Retreat is appropriate for all persons involved in biorepository research: institutional research directors, IRB coordinators, IRB members, legal counsel, principal investigators, hospitals and physicians providing biospecimens for research, and biorepository holders. While the Retreat will not discuss the technical aspects of maintaining a biorepository, biorepository holders are encouraged to come to the Retreat to understand the legal and ethical issues encountered by providers and others who provide biospecimens.







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## Program Agenda

<b>8:00 – 9:00 a.m.</b>	<b>Registration and networking breakfast</b>
<b>9:00 – 9:30 a.m.</b>	<b>Welcome and Introductions</b> <b>Dawn C. Schroeder, D.D.S., MA</b> Executive Director, Arizona Biomedical Research Commission <b>William A. Read, Ph.D.</b> Vice President for Research & Technology, Flinn Foundation <b>Kristen B. Rosati, J.D.</b> Partner, Coppersmith Gordon Schermer & Brockelman PLC
<b>9:30 – 10:15 a.m.</b>	<b>Keynote Speaker: The Power of Biorepositories for Research</b> <b>Anna D. Barker, Ph.D.</b> Deputy Director for Advanced Technologies and Strategic Partnerships, National Cancer Institute
<b>10:15 – 10:30 a.m.</b>	<b>Break</b>
<b>10:30 – 11:15 a.m.</b>	<b>Biorepositories in Arizona: Our Local Landscape</b> <b>Robert J. Penny, M.D., Ph.D.</b> Chairman and CEO, Molecular Profiling Institute; Chief Operating Officer, Chief Medical Officer, Executive Director expO, International Genomics Consortium <b>Joseph Rogers, Ph.D.</b> President and Senior Scientist, Sun Health Research Institute <b>Anil Prasad, M.D.</b> Assistant Professor of Clinical Pathology, University of Arizona Health Science Center <b>Joan Shapiro, Ph.D.</b> V.P. Research and Development, St. Joseph's Hospital and Medical Center
<b>11:15 – 11:45 a.m.</b>	<b>IRB Review of Biorepository Research</b> <ul style="list-style-type: none"><li>• Addressing regulatory compliance at three levels: the specimen source, the biorepository, and the provision of biospecimens for research protocols</li><li>• Evaluating when IRB review is required and whose IRB should perform the review</li><li>• Proposed guidance for IRB review of biorepository specimen collection, storage and dissemination</li></ul> <b>P. Pearl O'Rourke, M.D.</b> Director of Human Research Affairs, Partners HealthCare Systems, Inc.

*Continued on next page*

**11:45 a.m. – 1:00 p.m. Lunch and Program**

**Keynote Speaker: National Efforts to Encourage Biobanking**

**Greg Simon, J.D.**

President, FasterCures/The Center for Accelerating Medical Solutions

FasterCures, whose mission is to identify and implement solutions to accelerate the process of discovery and clinical development of new therapies, has established "BioBank Central," a Web site containing information about the logistical, technical, ethical, financial, intellectual property, and IT challenges facing biobanks and news about biorepositories and their role in research and drug development.

**1:00 – 2:30 p.m.**

**Protecting Donors and Their Communities**

- Seeking informed consent from donors
- Dealing with donor requests for withdrawal of tissue
- Communication of research findings to donors
- Ensuring donor privacy: HIPAA and Common Rule regulatory requirements
- Involving American Indian participants and communities

**Edward B. Goldman, J.D.**

Associate Vice President and Deputy General Counsel, Office of the General Counsel, University of Michigan Health System

**Rebecca Dahl, Ph.D.**

Director, Human Subjects Protection Program, University of Arizona

**Donald K. Warne, M.D., M.P.H.**

Clinical Professor Indian Legal Program, Arizona State University Sandra Day O'Connor College of Law

**Kristen B. Rosati, J.D.**

Partner, Coppersmith Gordon Schermer & Brockelman PLC

**2:30 – 2:45 p.m.**

**Break**

**2:45 – 4:15 p.m.**

**The Business of Biospecimens: Tissue Transfer**

- Drafting tissue transfer policies
- Drafting Material Transfer Agreements, Clinical Trial Agreements, and other agreements to transfer tissue
- Understanding issues for non-profit and tax-exempt organizations
- Recognizing and handling the intellectual property issues
- Dealing with potential ownership issues

**Gary Marchant, J.D., Ph.D., M.P.P.**

Executive Director and Faculty Fellow, Center for the Study of Law, Science, and Technology; Lincoln Professor of Emerging Technologies, Law and Ethics, Arizona State University Sandra Day O'Connor College of Law

**Manoja Lecamwasam, Ph.D.**

Director, Intellectual Property and Innovation, St. Joseph's Hospital and Medical Center

**Catherine Horrigan, J.D.**

Of Counsel, Research, Cleveland Clinic Foundation

**4:15 – 4:30 p.m.**

**Next Steps: Convening the Biorepository Policy Development Committee**

- Open invitation to participate in development of a template policy, informed consent document, HIPAA authorization form, and training module on biorepository research
- Timeline and first meeting of committee